IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

LYNE LABORATORIES, INC., FRESENIUS USA MANUFACTURING, INC., and FRESENIUS MEDICAL CARE HOLDINGS, INC. Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Lyne Laboratories, Inc. ("Lyne"), Fresenius USA Manufacturing, Inc. (FUSA), and Fresenius Medical Care Holdings, Inc. ("FMCHI") (together, "plaintiffs") for their Complaint against Lupin Limited ("Lupin") and Lupin Pharmaceuticals, Inc. ("LPI") (jointly and severally, "defendants") allege as follows:

THE PARTIES

1. Lyne is a Massachusetts corporation having its principal place of business at 10 Burke Drive, Brockton, Massachusetts.

2. FUSA is a Delaware corporation having its principal place of business at 920 Winter Street, Waltham, Massachusetts.

3. FMCHI is a New York corporation having its principal place of business at 920 Winter Street, Waltham, Massachusetts.

4. Upon information and belief, Lupin is a company organized and existing under the laws of India, having its principal place of business at C/4 Laxmi Towers, Bandra Kurla

Complex, Bandra (East), Mumbai, 400 051, Maharashtra, India; and its registered office at 159, C.S.T. Road, Kalina, Santacruz (East), Mumbai - 400 098, Maharashtra, India.

5. Upon information and belief, LPI is a Virginia corporation having its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. It is a wholly-owned subsidiary, alter ego, and U.S. Agent of Lupin. Upon information and belief, LPI is the U.S. Agent for Lupin for purposes including but not limited to making regulatory submissions to the United States Food and Drug Administration ("FDA").

6. On information and belief, Lupin appointed LPI as its authorized U.S. Agent for purposes of that submission, and LPI acted as such.

NATURE OF ACTION

7. This is a civil action for declaratory and injunctive relief against Lupin and LPI for patent infringement under the Food and Drug and Patent Laws of the United States, arising from Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 203143 to the Food and Drug Administration ("FDA") for approval to market a generic copy of FMCHI's Phoslyra® calcium acetate oral solution.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.§§ 1331, 1338(a), 2201 and 2202. Specifically, on information and belief, Lupin and LPI as its U.S. Agent included in ANDA No. 203143 a certification under Paragraph IV of Section 505(j)(2)(A)(vii) of the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman Act"), with respect to United States Patent Nos. 8,591,938 B2 and 8,592,480 B2. *See* 21 U.S.C. § 355(j)(2)(A)(vii). Under the Hatch-Waxman Act, the filing of a so-called "Paragraph IV certification" with respect to a patent constitutes an act of patent infringement

under 35 U.S.C. § 271(e)(2)(A). Accordingly, this case presents a question of federal law over which the Court has exclusive subject matter jurisdiction.

9. This Court has personal jurisdiction over both Lupin and LPI, at least by virtue of the fact that defendants conduct business in the Commonwealth of Massachusetts, have availed themselves of the rights and benefits of Massachusetts law, and have engaged in substantial and continuing contacts with the Commonwealth.

10. Lupin and LPI as its wholly-owned subsidiary, alter ego and U.S. Agent are in the business of making and selling drug products in the United States.

11. Lupin and LPI as its wholly-owned subsidiary, alter ego and U.S. Agent conduct business in the Commonwealth of Massachusetts and sell various drug products in the Commonwealth of Massachusetts.

12. Upon information and belief, Lupin is in the business of developing, manufacturing, marketing, and selling generic drugs. On information and belief, Lupin established LPI for the purpose of distributing, marketing and selling its generic drug products throughout the United States, including in this District. Lupin maintains an Internet website at the URL www.lupinworld.com at which it represents that it has a representative office at Harborplace Tower, 111 South Calvert Street, 21 Floor, Baltimore, Maryland, the principal place of business of LPI.

13. On information and belief, LPI and Lupin operate as an integrated, unitary business by representing to the public that the activities of Lupin and LPI are directed, controlled, and carried out by a single entity, namely, Lupin, headquartered in India.

14. Lupin and LPI as its U.S. Agent participated in, contributed to, aided, abetted, and/or induced the submission to the FDA of the ANDA at issue in this case.

15. LPI is registered to do business in Massachusetts.

16. Upon information and belief, LPI has appointed National Registered Agents, Inc. of 155 Federal Street, Suite 700, Boston, MA, as its registered agent for the receipt of service of process.

17. Venue is proper in this jurisdiction under 28 U.S.C. §§ 1391 and 1400(b).

INFRINGEMENT BY LUPIN AND LPI

18. Lyne is the assignee of U.S. Patent No. 8,591,938 B2 (the ’938 patent) entitled “Liquid Compositions of Calcium Acetate,” which the U.S Patent and Trademark Office duly and legally issued on November 26, 2013. A true and correct copy of the ’938 patent is attached as Exhibit A. The claims of the ’938 patent are valid and enforceable. FUSA is an exclusive licensee of the ’938 patent.

19. Lyne is the assignee of U.S. Patent No. 8,592,480 B2 (the ’480 patent) entitled “Liquid Compositions of Calcium Acetate,” which the U.S Patent and Trademark Office duly and legally issued on November 26, 2013. A true and correct copy of the ’480 patent is attached as Exhibit B. The claims of the ’480 patent are valid and enforceable. FUSA is an exclusive licensee of the’480 patent.

20. FMCHI, d/b/a Fresenius Medical Care North America, is the holder of New Drug Application (“NDA”) No. 022581 for Phoslyra®, upon which ANDA No. 203143 is based.

21. The FDA’s official publication of approved drugs (“the Orange Book”) lists the ’938 and ’480 patents under Phoslyra®.

22. By operation of law, the submission of ANDA No. 203143 by Lupin and its authorized U.S. Agent LPI constitutes infringement of the ’938 and ’480 patents, because defendants included within the ANDA a Paragraph IV certification to the effect that the ’938 and ’480 patents are invalid, unenforceable, or would not be infringed by their proposed generic copy

of FMCHI's Phoslyra® calcium acetate oral solution. The submission of this certification by defendants constitutes an act of infringement of one or more claims of the '938 and '480 patents under the Hatch-Waxman Act and the Patent Act, because the proposed generic drug is covered by one or more claims of the '938 and/or '480 patents, and/or because its use is covered by one or both of those patents. *See* 35 U.S.C. § 271(e)(2)(A).

23. Upon information and belief, defendants intend to, and will, engage in the commercial manufacture, use and sale of their generic calcium acetate oral solution promptly upon receiving FDA approval to do so.

24. By letter sent to FMCHI and Lyne ("the Notice Letter"), Lupin and its authorized U.S. Agent LPI notified FMCHI and Lyne of the ANDA filing seeking approval to engage in the commercial manufacture, use, and sale of generic calcium acetate oral solution before the expiration dates of the '938 and '480 patents.

25. In the Notice Letter, Lupin notified FMCHI and Lyne that its ANDA contained a Paragraph IV certification alleging that in its opinion the '938 and '480 patents are invalid and/or unenforceable and/or would not be infringed by defendants' proposed commercial manufacture, use or sale of its generic calcium acetate oral solution.

26. This Complaint is being filed before the expiration of the forty-five days from the date FMCHI and Lyne received the Notice Letter.

Count I (Infringement of the '938 Patent)

27. Each of the preceding paragraphs 1 to 26 is incorporated as if fully set forth herein.

28. Defendants' submission of ANDA No. 203143 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic calcium acetate oral solution prior

to the expiration of the ’938 patent constitutes infringement of one or more claims of the ’938 patent under 35 U.S.C. § 271(e)(2)(A).

29. Upon FDA approval of ANDA No. 203143, defendants will further infringe one or more claims of the ’938 patent by making, offering to sell, importing, or selling their proposed generic calcium acetate oral solution in the United States, and importing such solution into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by this Court.

30. Defendants had notice of the ’938 patent prior to the filing at the time of its infringement. Their infringement has been, and continues to be, willful and deliberate.

31. Plaintiffs will be substantially and irreparably damaged and harmed if infringement of the ’938 patent by Lupin and LPI is not enjoined. Plaintiffs do not have an adequate remedy at law.

Count II (Infringement of the ’480 Patent)

32. Each of the preceding paragraphs 1 to 31 is incorporated as if fully set forth herein.

33. Defendants’ submission of ANDA No. 203143 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic calcium acetate oral solution prior to the expiration of the ’480 patent constitutes infringement of one or more claims of the ’480 patent under 35 U.S.C. § 271(e)(2)(A).

34. Upon FDA approval of ANDA No. 203143, defendants will further infringe one or more claims of the ’480 patent by making, offering to sell, importing, or selling their proposed generic calcium acetate oral solution in the United States, and importing such solution into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by this Court.

35. Defendants had notice of the ’480 patent prior to the filing at the time of its infringement. Their infringement has been, and continues to be, willful and deliberate.

36. Plaintiffs will be substantially and irreparably damaged and harmed if infringement of the ’480 patent by defendants is not enjoined. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Accordingly, plaintiffs respectfully request the following relief:

a. A judgment declaring that defendants have infringed the ’938 and ’480 patents, and that the making, using, selling, offering to sell, or importing of their generic calcium acetate oral solution will infringe the ’938 patent and ’480 patents;

b. A judgment providing that the effective date of any FDA approval for Lupin and LPI to make, use or sell their generic calcium acetate oral solution be no earlier than the later of the dates on which the ’938 and ’480 patents expire;

c. A judgment permanently enjoining defendants from making, using, selling, offering to sell, or importing their generic calcium acetate oral solution until after the expiration of the ’938 and ’480 patents;

d. If defendants engage in the commercial manufacture, use, offer to sell, or sale of their generic calcium acetate oral solution prior to the expiration of the’938 or ’480 patents, a judgment awarding plaintiffs damages or other monetary relief, increased to treble the amount found or assessed, together with interest;

e. Attorney’s fees in this action pursuant to 35 U.S.C. § 285;

f. Costs and expenses in this action; and

g. Such further and other relief as the Court may deem just and proper.

/s/ Lucas I. Silva
Lucas I. Silva, BBO # 673935
lsilva@foley.com
FOLEY & LARDNER LLP
111 Huntington Avenue, Suite 2600
Boston, Massachusetts 02199
Phone: (617) 342-4000
Fax: (617) 342-4001
Attorney for Plaintiff Lyne Laboratories, Inc.

Of counsel:
Liane M. Peterson
lpeterson@foley.com
FOLEY & LARDNER LLP
3000 K Street, NW, Suite 600
Washington, DC 20007
Phone: (202) 945-6116
Fax: (202) 672-5399

/s/ Sarah S. Burg
Stephen B. Deutsch, BBO # 122000
sdeutsch@foleyhoag.com
Claire Laporte, BBO # 554979
claporte@foleyhoag.com
Sarah S. Burg, BBO # 683245
sburg@foleyhoag.com
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts 02210
Phone: (617) 832-1000
Fax: (617) 832-7000

Attorneys for Plaintiffs Fresenius USA Manufacturing, Inc. and Fresenius Medical Care Holdings, Inc.

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